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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,211	07/25/2001	Michel Kohl	9997.19USI1	5895

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EXAMINER	
VENCI, DAVID J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,211	KOHL ET AL.	
	Examiner	Art Unit	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12-06-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *2-10,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1 and 11-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04-23-04* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/171,819.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 1 and 11-27, in the reply filed on December 6, 2004, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The declaration is defective because the specification to which the declaration is directed has not been adequately identified. See MPEP § 602. In addition, the declaration does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Priority

Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 09/171,819 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy.

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or

continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Drawings

Drawings were received on April 23, 2004. These drawings are not acceptable because the drawings are handwritten. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claim is directed to non-statutory subject matter. Claim 11 does not appear to set forth any steps involved in a process, thereby resulting in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 11-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The specific claim rejections under 35 USC 112, second paragraph, set forth infra, may be considered relevant to other claims not explicitly mentioned, as deemed reasonably appropriate.

In claim 1, the recitation of "at least" is indefinite because it is not clear what size, number, or degree is intended. In addition, the recitation of "partially constitutive" is indefinite because it is not clear how the lactam derivative is related to or dependent on a conjugating arm. In addition, the recitation of "conjugating arm" lacks antecedent basis and is indefinite because it is not clear whether "conjugating arm" coexists independently from the hapten entity and lactam derivative entity.

In claim 11, the recitation of "Method for the immunoassay of a hapten involving a β-lactam derivative-based inhibitor-hapten conjugate" and "a β-lactam derivative-based inhibitor-hapten conjugate" and "inhibitor-hapten conjugate" lack antecedent bases in claim 1. In addition, the recitations of "the free hapten" and "the recognition" and "detection and/or quantification means" lack antecedent bases. In addition, the recitation of "capable" is indefinite because it is not clear whether language subsequent to "capable" contain required claim limitations. The recitation of "protein receptor site" is indefinite because it is not clear where said "site" is located in relation to other components of the method, or whether said "site" refers to a spatial arrangement of the various components of the method, or whether said "site" refers to a location on a protein. In addition, it is not clear whether said "protein receptor" is a receptor for a protein, or whether/how a β-lactam moiety binds to such a receptor for a protein. In addition, the recitation of "and/or" is indefinite because it is not clear whether language subsequent to "and/or" contain required claim limitations.

In addition, claim 11 is indefinite because the claim does not appear to set forth any positive steps delimiting how this method is actually practiced. It is unclear what method/process applicant is intending to encompass. In addition, the recitation of conditional language "when unbound to said antibody" does not create a positive or negative claim limitation and is considered indefinite.

In claim 12, the recitation of "related to" is indefinite because, absent structural definition, it is not clear what relationship or connection is required between "conjugate binding" and "enzyme activity." In

addition, the recitation of "the modulation" lacks antecedent basis and is indefinite because, absent structural definition, it is not clear what steps, if any, are required in said "modulation" process.

In claim 13, the recitation of "the immunoassay in an homogeneous phase of a hapten" lacks antecedent basis in claim 11 and appears to have an grammatical error. In addition, the recitation of "related to" is indefinite because it is not clear what members are "related" or what relationship or connection is required. In addition, the recitation of "the enzymatic activity" lacks antecedent basis.

In claim 15, the Markush members are not clearly stated. Currently, claim 15 recites a single Markush group consisting of class C β-lactamases from three bacteria strains. It is not clear whether three Markush groups are intended.

In claim 16, the recitation of "corresponding to" is indefinite because it is not clear what members are "corresponding" or what relationship or connection is required. In addition, the recitation of "capable" is indefinite because it is not clear whether language subsequent to "capable" contains required claim limitations. In addition, the recitation of "the bound quantity" lacks antecedent basis. In addition, the recitation of "modulated" is indefinite because, absent structural definition, it is not clear what steps, if any, are required in said "modulation" process. Claim 16 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The preamble of claim 16 recites a "method for the immunoassay of a hapten involving a "β-lactam derivative-based inhibitor-hapten conjugate." However, the final step of claim 16 merely recites the step of adding a penicillin detector to the solution and binding the penicillin detector to the conjugate. It is not clear how adding a penicillin detector to the solution and binding the penicillin detector to the conjugate amounts to a "method for the immunoassay of a hapten."

Claim 17 contains several trademark/trade names. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the

requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe a "penicillin detector" and, accordingly, the identification/description is indefinite.

In claims 22-23, it is not clear how a "class B β-lactamase" is used in the method of claim 11 or whether/how such a component would affect the immunoassay.

In claim 24, the recitation of "the hydrolysis rate" lacks antecedent basis.

In claim 25, the recitation of "the revealing reagent" lacks antecedent basis and is indefinite because it is not clear what is being revealed or how a reagent is revealed or the steps required, if any, in the "the revealing" process. The recitations of "appropriate pH" and "the working pH" lack antecedent bases.

In claims 24-25, it is not clear how the recited limitations are incorporated into the method of claim 11, or whether the step(s) are performed prior to or during the method of claim 11, or whether the step(s) are performed in the same solution as the method of claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenquist & Walter (US 4,442,204) in view of Bieniarz et al. (US 4,978,613).

Greenquist & Walter teach an immunoassay method of a hapten (see Abstract, "hapten") involving a label derivative-based (see Abstract, "specific binding analog thereof") inhibitor-hapten (see col. 6, lines 5-13, "chemical reactivity") conjugate (see Abstract, "labeled conjugate"), wherein the label derivative is at least partially constitutive of the conjugating arm (see e.g. Fig. 7, "XII"), wherein said label derivative binds competitively (see Fig. 1, "Competitive") with the free hapten to be assayed (see Fig. 1, "drug assayed") to an anti-hapten antibody (see Fig. 1, "antibody"), wherein said conjugate binds to a protein receptor site (see Fig. 1, "enzyme") for the label moiety (see col. 7, lines 30-34, "the label is selected so that the labeled conjugate is a substrate for an enzyme"), the antibody-bound conjugate being unable to bind to said receptor, owing to steric hindrance (see Fig. 1, "competitive binding reaction", see col. 7, lines 30-34, "the ability of the enzyme to act on the substrate-labeled conjugate is affected, either in a positive or negative sense, by binding of the labeled conjugate with its binding partner"), wherein the recognition of the conjugate binding to the receptor (see Fig. 1, "fluorescent product") is associated with a detection means (see Abstract, "visual observation or instrument means").

Greenquist & Walter do not teach a β-lactam label.

However, Bieniarz et al. teach the use of β-lactam derivatives (see col. 2, formula I) in lactam-lactamase immunoassays (see col. 1, lines 65+, "enzyme immunoassays which use β-lactamase as a label"). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the inhibitor-hapten conjugate of Greenquist & Walter with a β-lactam label because Bieniarz et al. teach that lactam-lactamase detection systems are very sensitive due to the very high turnover of lactamases, are easily available in high purity, have pH optima compatible with immunoassays, are relatively stable, have low molecular weight, are inexpensive, and are usually absent in body fluids (see col. 1, lines 23-29).

With respect to claim 12, Greenquist & Walter teach a reporter substrate (see e.g. Fig. 7, "XII").

With respect to claim 13, Greenquist & Walter describe a reporter enzyme having an active site for two substrates entering into competition (see col. 8, lines 12-23, "enzyme inhibitor", "The rate of the resulting enzymatic reaction is measurable by... an ultimately detectable signal").

With respect to claims 14-15, Bieniarz et al. teach the use of β-lactamase from Enterobacter cloacae (see col. 15, lines 15-16).

With respect to claims 16-17, Bieniarz et al. teach the use of a β-lactamase penicillin detector.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenquist & Walter (US 4,442,204) and Bieniarz et al. (US 4,978,613) as applied to claims 1 and 11-12, and further in view of Galleni et al. 255 Biochem. J. 123 (1988) (abstract only).

Greenquist & Walter and Bieniarz et al. teach an immunoassay method of a hapten as substantially described supra. The aforementioned references do not teach nitrocefin or cephalexin reporter substrates.

However, Galleni et al. teach the use of nitrocefin and cephalexin as substrates for class C beta-lactamases. Therefore, it would have been obvious for a person of ordinary skill in the art to modify the lactam-lactamase detection system of Greenquist & Walter and Bieniarz et al. with the use of nitrocefin or cephalexin because Galleni et al. teach that both substrates worked swell with high turnover up to 5000 s^{-1}.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenquist & Walter (US 4,442,204) and Bieniarz et al. (US 4,978,613) as applied to claims 1 and 11, and further in view of Hrubes et al. (CS 27701).

Greenquist & Walter and Bieniarz et al. teach an immunoassay method of a hapten as substantially described supra. The aforementioned references do not teach a substance for removing possible interference.

However, Hrubes et al. teach the use of sodium azide in immuno-analysis (see Abstract). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the lactam-lactamase detection system of Greenquist & Walter and Bieniarz et al. with the use of sodium azide because Hrubes et al. teach that solutions containing, inter alia, sodium azide are useful for non-specific reaction suppression in immuno-analysis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 11-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 5-10 of Kohl et al. (US 6,436,649) in view of Bieniarz et al. (US 4,978,613).

Claims 1-2 and 5-10 of Kohl et al. recite a competitive immunoassay of a hapten using an inhibitor-hapten conjugate (see claim 1). The inhibitor-hapten conjugate of Kohl et al. necessarily teaches a conjugate "wherein the [label] is at least partially constitutive of the conjugating arm," and would be so recognized by persons of ordinary skill in the art. Kohl et al. do not recite a β-lactam derivative conjugate.

However, Bieniarz et al. teach the use of β-lactam derivatives (see col. 2, formula I) in lactam-lactamase immunoassays (see col. 1, lines 65+, "enzyme immunoassays which use β-lactamase as a label"). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the inhibitor-hapten conjugate of Kohl et al. with a β-lactam derivative label Bieniarz et al. teach that lactam-lactamase detection systems are very sensitive due to the very high turnover of lactamases, are easily available in high purity, have pH optima compatible with immunoassays, are relatively stable, have low molecular weight, are inexpensive, and are usually absent in body fluids (see col. 1, lines 23-29).

With respect to claims 14-15, Kohl et al. recite a β-lactamase from E. coli (see claim 1).

With respect to claims 16-17, Kohl et al. recite a penicillin detector (see claim 1, "β-lactamase").

With respect to claims 18-19, Kohl et al. recite nitrocefin and cephalexin reporter substrates (see claim 7).

With respect to claims 20-21, Kohl et al. recite decontaminating agents (see claim 2).

Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of Kohl et al. (US 6,436,649) in view of Bieniarz et al. (US 4,978,613) as applied to claims 1, 11, 20-21, and further in view of Hrubes et al. (CS 27701).

Claim 22 of Kohl et al. recites a competitive immunoassay of a hapten using an agent for removing possible interference. Kohl et al. do not recite the use of sodium azide.

However, Hrubes et al. teach the use of sodium azide in immuno-analysis (see Abstract). Therefore, it would have been obvious for a person of ordinary skill in the art to modify the lactam-lactamase detection system of Kohl et al. and Bieniarz et al. with the use of sodium azide because Hrubes et al. teach that solutions containing, inter alia, sodium azide are useful for non-specific reaction suppression in immuno-analysis.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/26/04